SECTION 12: 510(k) SUMMARY

This summary of 510(K) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Name, Address, Phone and Fax number of Applicant

Guidant Corporation
Cardiac Surgery
3200 Lakeside Drive
Santa Clara, CA 95054

Tel: (408) 845-1910
Fax: (408) 845-1855

B. Contact Person

Debbie Cogan
Regulatory Affairs Associate

C. **Date Prepared**

December 6, 2002

D. Device Name

Trade Name: Syncrus Internal Cardioversion System
Classification Name: ELECTRODE, PACING AND CARDIOVERSION, TEMPORARY, EPICARDIAL
Product Classification Code: NHW
Device Classification: Class 2
Establishment Registration: 2953148

E. Device Description

The Syncrus System consists of three components:

- Three temporary heart wires sutured onto the heart during open-heart surgery. The wires include a unipolar defibrillation heart wire (left atrium), a bipolar pacing/sensing heart wire (right or left ventricle) and a tripolar defibrillation and pacing and sensing heart wire (right atrium).

- An attenuator box (External Defibrillator Interface - Module EDIM). The EDIM attenuates the delivered energy from a standard, low energy defibrillator by 97% (50 - 360 Joules to 1.3 – 11.5 Joules).
- A cardioversion extension cable, which connects the defibrillation heart wires to the EDIM.

The user must supply an external, low-energy defibrillator that is capable of synchronized cardioversion, an external pacemaker, and temporary patient cables to connect the pacemaker to the patient. The Syncrus System is designed to perform the following cardiac rhythm management functions:

- Atrial pacing and electrocardiogram sensing
- Ventricular pacing and electrocardiogram sensing
- Atrial defibrillation using low energy, synchronized cardioversion.

F. Intended Use

The Guidant SYNCRUS™ Internal Cardioversion System is indicated for use in post-operative cardiac surgery patients who require temporary atrial or ventricular pacing/sensing and/or atrial cardioversion.

G. Substantial Equivalence

Guidant proposes that the Syncrus System is substantially equivalent to the Syncrus System (K020701). The subject device is substantially equivalent to the predicate device with regard to intended use, indications, device characteristics, method of use, labeling, materials, and safety feature.

H. Device Testing Results and Conclusions

Guidant Cardiac Surgery performed bench testing to confirm that the Syncrus System may be used with a biphasic defibrillator. All bench testing results met specified requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 4 2003

Guidant Corporation
c/o Ms. Debbie Cogan
Regulatory Affairs Associate
Guidant Cardiac Surgery
3200 Lakeside Drive
Santa Clara, CA 95054

Re: K024071
Trade Name: Guidant Syncrus™ Internal Cardioversion System
Regulation Number: 21 CFR 870.3680
Regulation Name: Electrode, Pacing and Cardioversion, Temporary, Epicardial
Regulatory Class: Class II (two)
Product Code: NHW
Dated: January 10, 2003
Received: January 15, 2003

Dear Ms. Cogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K024071

Device Name: Guidant Syncrus™ Internal Cardioversion System

Indications For Use: The Guidant SYNCRUS™ Internal Cardioversion System is indicated for use in post-operative cardiac surgery patients who require temporary atrial or ventricular pacing/sensing and/or atrial cardioversion.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR (Per 21 CFR 801.109) Over-The-Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K024071